EDITED TRANSCRIPT

Steven E. Hyman, M.D.: Remarks

NIMH Constituency Outreach and Education Program

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Good morning.

I am delighted to have this opportunity to meet with and hear from you. I would like to spend several minutes describing current, high visibility issues that affect all of us in the mental health field, and then allow time for us to interact.

Although the past few years have been incredibly exciting and promising for the National Institute of Mental Health (NIMH) and the mental health field, it also has been a perilous time insofar as the more visible we are in the public eye, the more vulnerable we are to being buffeted by political forces. We deal frequently with headline-making and potentially highly politicized issues ranging from insurance parity to drug treatments for childhood mental disorders to the relationship between mental disorders and violence. It is very important that we act and move forward on a foundation of solid data that will ensure that we are on the right course for designing, recommending, and implementing policies that will make a difference for people with mental disorders; in the absence of data, we risk allowing prejudiced and stigmatizing views to hold sway.

I want to comment on several hot issues and then consider how a partnership between those of us at NIMH and our different advocacy groups and advisory groups can enhance the quality of our information base and help us all stay on the right track.

Let me begin by reviewing an experience I had last Thursday, when I had the opportunity to testify before a Senate committee that was considering the reauthorization of the Parity Act, often called the Domenici-Wellstone Bill. This bill, as you know, mandated that employee insurance programs that cover 50 or more employees and that offer mental health benefits could not set different yearly or lifetime caps for mental health benefits as opposed to general medical benefits.

Our national experience over the past couple of years has made it clear that the vast majority of companies that fall under the provisions of the Domenici-Wellstone bill are, at best, following the letter

of law but not the spirit. In fact, this parity law has been, to a great extent, defeated in that yearly and lifetime dollar caps have been replaced by limits on hospital days and outpatient visits and changes in co-payments. The end result is that we do not yet have true parity at the national level.

At present, some 30 States have enacted parity legislation. The laws are extremely variable from State to State. Some States have succeeded in achieving the goals of improved access and true parity; in other instances, State laws fall short of the federal standards. And, of course, 20 states still have nothing other than the federal law.

My invitation to testify presented an opportunity to describe several challenges that the question of parity poses to the mental health field and to call attention to our progress in responding to these challenges. A first is to establish that mental disorders are in all ways equivalent to and as worthy of treatment as any other illness. I believe that one of the advantages of a strong NIMH is that the research we support and conduct ultimately is aimed toward treatment and, hopefully, toward cures and prevention; as we work toward those ultimate goals, ongoing research provides data for policy makers who are grappling with immediate public policy questions. Thus, the first point I made in my testimony is that all available evidence from biomedical and behavioral research points to the futility of attempting to draw a line between "mental disorders" and any other illness that affects humanity.

Indeed, I wish that we had a term other than "mental" disorders because that term, given its long history of misuse and misunderstanding, suggests that the processes of illness are going on somewhere other than in an organ of our body, the brain. We need to keep making the point that mental disorders are disorders of an organ, the brain. We are continuing to hammer this point home and, with research data, we are making considerable progress.

Even after we make the point that these are real, medical disorders, the next issue that frequently comes to the fore is "Can we make accurate, meaningful diagnoses?" Then come questions that one rarely hears in the context of cancer or heart disease: "Are our treatments effective and cost effective?" I would never want to pit disease against disease, but it is interesting that the mental health field gets undue skepticism about the effectiveness of treatments. How do we respond?

Consider the question about making diagnoses. The truth is, the tools we have for diagnosing disorders and diagnostic categories themselves are far from perfect. Lacking reliable biological

markers, we still rely on entirely on behavioral criteria – but, in this, we are not unique. There are many other areas of medicine, which are fully covered under health insurance, where diagnoses are far from certain. Just today, for example, the New York Times' *Science of the Times* section ran an article recounting the incredible debate going on over what are the boundaries of Lyme disease.

I unfortunately have personal experience with questions about when diagnosis truly defines illness and whether effective treatments are available. I have a bad back. Apart from pointing to a design flaw in humans, back problems underscore, in a general medical context, questions about the boundaries of musculoskeletal pains and distress that are worthy of medical intervention. I have learned that the best treatment for spinal disc disease is to tough it out. That doesn't sound like a really modern, cost effective treatment – and is far more primitive than treatments for mental illness – but how often does one hear the diagnosis of backache or a treatment challenged? The truth is that, in most cases, an MRI scan of disk disease provides no information relevant to treatment; abnormalities very often have little correlation with clinical symptoms. This brief example accentuates how the mental health field is held to a different standard.

At the Senate parity hearing, another facet to the diagnosis issue was seen in the written statement of the insurance industry, which cited diagnosis of attention deficit hyperactivity disorder as an example of a diagnosis that is a catastrophe. When we hear such an assertion, we ought to be very clear that there is little problem for a professional with appropriate expertise and time to make a clinical diagnosis. Rather, the problem is in the *application* of diagnostic criteria, by the diverse medical and health care personnel who are seeing our children. That is, many family doctors who are making these diagnoses don't have the training or the time to do a proper workup, make a correct diagnosis, implement a treatment plan, and monitor the course of treatment.

The problems we see in doctors failing to apply and adhere to diagnostic and practice guidelines are, once again, not unique to mental health. In terms of treatment, my favorite example is the decade-old recognition that peptic ulcer disease is caused by a bacterial infection, an organism called *helicobacter pylori*. It has taken more than ten years to get the majority of primary care physicians to prescribe antibiotics for peptic ulcer disease. And despite enormous attempts to get these kinds of guidelines fully adopted by the medical treatment community, it is still not fully accomplished. Again, we

are not unique, but we, again, are often held to unique standards because of the stigmatizing history from which we are emerging.

What kinds of data do we need to respond to these various challenges? One useful and powerful data set is found in the Global Burden of Disease study, a landmark research project conducted for the World Bank and the World Health Organization with Harvard University investigators. The study showed that major depression is the *leading* cause of disability in developed countries such as the United States. Also among the top ten causes of disability are schizophrenia, manic depressive illness, and obsessive compulsive disorder.

From other credible research sources, we also have reliable data that people with untreated or inappropriately treated major depression experience between 1-1/2 to 3 times more disability days – that is, absences from work -- than people who don't have this illness. Research also has shown that appropriate treatment of major depression permits the majority of people with the illness to return to work and to function fully in all domains of their lives. Data regarding ability to return to work and function illustrate an "indirect cost offset" for treating depression. There also are direct cost offsets. Research has shown that the use of general medical services by people with major depression is some 50 percent higher than use by people in the population at large who do not have this illness. This excessive and expensive use of general medical services falls to the population average when we recognize and treat depression effectively.

Although I am pleased that we increasingly have the research capacity and the data to respond to the questions – Are mental disorders real? Can they be diagnosed? Do effective treatments exist? – I want to emphasize that similar questions are not asked of other diseases as a prerequisite to getting equitable coverage.

While it is important for NIMH to obtain this kind of data and present it to policy makers, it also is critically important for advocacy groups to be conversant with the same data. By being educated, by having data at your fingertips, you are in a much better position to argue at the local, state, and national level about issues such as equity in reimbursement.

As important as it is for NIMH to give you the research evidence that we obtain, it is equally important that we hear from you. If we don't have an effective discourse with our advocates, we may

also not understand what is needed, for example, to convince policy makers at the state level of the fundamental equality of mental disorders with other disorders and the fact that it makes no sense at all not to cover treatment for these disorders. We cannot have healthy children able to learn in school, we cannot have a healthy work force unless we have appropriate interventions with access for the widest possible number of Americans.

A second example of where we have been very much in the news yet again has to do with the use of psychotropic medications by children. Here too, we have seen a very polarized debate. The most recent episode was initiated by a paper published in *JAMA*, the Journal of the American Medical Association, which showed sharply increased rates of use, by pre-school children, of several prescribed medications: methylphenidate or Ritalin; tricyclic antidepressants; and clonidine. The *JAMA* paper told us nothing about the diagnoses these children had or about follow-up; rather, it just focused on prescription rates. Despite the fact that it shed little light on what was actually going on in the clinic, some people immediately took umbrage and, basically, we were left again in a situation where much of the media wanted to have a referendum on the headlines: Are medications good or bad for children?

I think all of you realize that discussion, not to mention public policy, needs to be based on data and not upon philosophically based feelings as to whether a medicine or a behavioral intervention is "good" or "bad." Some medicines are good for some people some of the time. And all interventions have costs and side effects. The real question is how they are used. Who is seeing our children, who is making diagnoses, what is their training? Will a child be seen by someone who is constrained to a 7-minute visit or does the health care provider have the time to do a proper history, get the whole story? That entails, at the very least, finding out how a child is doing in multiple settings — at school, at home, with playmates. What is the procedure for following and monitoring an individual child through a course of treatment? What specific side effects is a child experiencing if he or she is receiving medication? Are doses being optimized? If a child's treatment plan also calls for psychotherapy, it is important to know that they and the family are actually participating. Too often, a doctor will make a referral, but no one shows up.

These are the critical issues and we collectively – that is, NIMH and all the groups with whom we work – need to refocus the debate and move it from abstract, sometimes almost apocalyptically

worded questions – Are our children being overmedicated? Are we applying pharmacologic shackles on exuberant boyhood? – to a focus on the underlying issues. *How* are our children being diagnosed? How are our children being treated? How are they being followed? What are their outcomes?

Much of the information that will do us the greatest service, will be obtained through a dialogue with the parents who live with these issues every day. The parents of kids who are really severely ill, disabled, perhaps behaviorally uncontrollable, and who are appropriately treated with medication, even very early in life, often may be made to feel as if there is something wrong with them; that is, they are made to feel guilty by inappropriate, sensationalistic headline writing.

I don't have all of the answers as to how we would engage parents in the needed dialogue, but I want to describe some of the steps we are taking in our research that I believe afford all members of the public various opportunities to communicate with and advise NIMH and the scientific community. In the next segment of this meeting you are going to hear about clinical trials so let me describe a new NIMH initiative that I believe will enhance communication among patients, front-line clinicians, and researchers.

Over the last several decades, the manner in which we generated data, for example, for treatment interventions for depression or childhood disorder went something like this. We would decide to study a form of psychotherapy or a medication or a combination of the two. We then would identify and recruit a study population at one of our outstanding academic research institutions. In order to make sure that there were not an unmanageable number of confounding variables, we would study a very pure population; that is, for depression it might be people between the ages of 20 and 60, and to make sure that there was not a lot of noise in the system, we would set other exclusion criteria focused on other co-existing medical conditions, perhaps gender, and other factors. For example, depression study participants could not have an anxiety disorder, which in reality is a very common fellow traveler with depression. They couldn't have heart disease, or drink excessively, and pretty soon the investigators would have a wonderful study population that looked nothing like the real world. In short, you had people who looked like they spent a lot of time at night studying the DSM-IV and modeling themselves after the descriptions, but they looked nothing like our family members or the people we see in primary care settings or specialty settings.

Secondly, based on the models that came from how drugs are approved by the FDA, a standard medication trial would last six weeks, eight weeks, and sometimes an enormously generous twelve weeks. Well, depression, you know, is a recurrent or sometimes chronic disorder. ADHD, you know, might be noticed at age 6 or younger and treatment often continues into adolescence and beyond. Clearly, six or eight weeks really is not a meaningful length of time for a study of antidepressants, mood stabilizers, or antipsychotic drugs. Many side effects are not foreseen or expected within such a short time frame; this is certainly the case for some of the side effects of lithium, used in treating bipolar disorder. Still, these very pristine, short term studies --the jargon term that you will be hearing more about is randomized, controlled efficacy trials – are critical and necessary. We need to do them to ascertain whether a new or refined treatment has any intrinsic efficacy or utility.

Although efficacy trials really are *necessary*, they are not sufficient. We need to do much more to improve the quality of treatment services available, potentially, to every or any person in the country. We need to study more representative populations, not just scholars of the DSM. We need to carefully monitor people on medications for longer periods of time. We need to know that treatments can be administered not only in academic centers, but also in real world settings, community clinics, and primary care settings. Without answers drawn from research, we can be we can be pretty certain that many people are never going to have the right treatment.

Then there is the question of the generalizability of treatments to children. It is obvious that psychotherapies – and particularly those used with children – need to be generalizable. There just are not enough child psychiatrists to deal with every community, and we need to know that even brief forms of talk or behavioral therapies can be administered with fidelity by primary health care providers. And, of course, this is true of medications. You may recall that prior to the SSRIs – that is, selective serotonin reuptake inhibitors, of which fluoxetine, or Prozac, was the prototype – the major antidepressant medication class that we had available, the tricyclics, often had very difficult-to-manage side effects. Often, when one would ask a person with depression to recall a prior episode of depression, they would immediately launch into a recital of the side effects of the medication they were on, not the symptoms or experience of illness. In fact, it often was so difficult to get people onto effective therapeutic doses of these drugs that many people remained in "treatment" for years on

subtherapeutic doses. They would be subject to adverse or troubling side effects, but would not experience the benefits of the medication.

Finally, we urgently need to be sure we are striving for and realizing outcomes that are defined in ways that are important to consumers and their families and employers, who very often are paying the insurance. Traditionally, we looked only at symptom reduction, but we need also to look at functional outcomes. Was a person with a serious depression able to return to work? Did they return to the same job and do well at it? What is their quality of life?

Unfortunately, these very sensible modifications of the standard efficacy trial -- that is, having a study population that more closely mirrors the diverse patients who will be prescribed various treatments; conducting a study in real world settings, and having additional outcome measures – all decrease the statistical power of a given study. It is understandable that many of our traditional research colleagues, investigators who indisputably have great expertise in conducting rigorous efficacy trials, were quite skeptical about would be learned were we to take clinical trials to the next level, to the next stage.

Given that reluctance, advocacy groups were critical in helping pave the way for NIMH to invest what is really an enormous amount of money – more than a hundred million dollars over the next five years – into what we are calling clinical effectiveness trials. This new generation of studies hopefully will provide critical data to families, to practitioners, and, above all, to insurers and employers and policy makers. Through the experiences of their memberships, many research advocacy groups really were among the first to see the importance and value of these studies. They knew that they were not getting treatment that worked in the same way as advertised, when the ads were based pretty much exclusively on narrow efficacy trials conducted at academic health centers. In order to help move our research field, we had to conduct research that is directly relevant to the consumers and purchasers of mental health services.

Another need that we understood to be critical if we were to maintain the momentum needed to broaden the scope of our research was to get people with direct experience of mental illness--whether as a consumer, a family member, or a front line practitioner – to help us review grant applications.

Again, as was the case with our interest in effectiveness as well as efficacy trials, this notion of broadening the composition of research review groups was quite controversial, at least with some of our traditional researchers. One professional association said in effect, "Well, it is no longer peer review if you have public members." It was clear to me that they really misunderstood our goal. We don't intend to invite someone from outside the scientific or clinical research community, who likely is in a completely different walk of life, and ask them to check the statistical models or power calculation that an investigator proposes to use. Rather, our first and foremost objective was to have people at the initial review table who will ask the "so what" questions. Often, a little distance can be a healthy and productive feature of a research proposal critique. We need to hear from people who can step back and ask straightforward questions, such as:

- If this pristine and highly rigorous study gets funded, will it make a noticeable difference in the quality of treatment?
- Is the study design appropriate in the sense of being participant friendly? Is the study one that I or a family member or a friend would actually enter and stay in?
- Does the informed consent document that the investigator wants to use provide me with a clear understanding of the goals and methods of the study or is it a legalistic kind of document, where I would feel that I am signing away my rights?

We have had this system of public members in place on several study sections for several review cycles now, and I can assure you it is not tokenism. At present, I would estimate that of a 20-member study section in the clinical or services arena, perhaps three are public members.

Although we are still in an era of mutual education between active researchers and public members, with everyone feeling their way as to what their role is in the judging of grant applications, I have observed the public members earning enormous respect. I see this as a great example of interaction among our many constituencies. I also am very pleased to have an increasingly broad cross section of our society involved in this most fundamental aspect of scientific priority setting; that is, selecting those grants that the NIMH should consider for funding.

Another topic that really demands dialogue with members of the public is that of sharing information. When we think about research dissemination, I know one thing that doesn't work is for NIMH to hand down information is what might be perceived as an arrogant fashion and sort of cram people's heads full of what we think is important. People such as yourselves -- consumers and families and practitioners and policy makers -- who live and work in the settings that we all are concerned with can contribute much to our thinking and planning. Even if we are not always going to agree on everything, at least we will be on the same page, we will be agreeing on the terms of the discussion, and, with some level of collegiality, we will be able to talk to the media, or talk to local policy makers.

So, you should not only be the recipients of what we produce but you need to really help us in many ways to develop our research portfolios and the information that flows from them so that together we can build a world in which people with mental illness, whether they are children or adults, are going to get the right interventions and the right treatment. Together, we can make sure that rash and inappropriate decisions or decisions based on old-fashioned and moralizing models of mental illness don't end up being the ground work for decisions that are going to affect all of us.

Now, before we open this up for discussion, I want to mention a completely separate topic, but one that is profoundly important to all of our efforts and that, of course, is the federal investment in research.

Many of you are probably aware that over the last three years, the Congress has been incredibly generous or, if you will, farsighted with regard to biomedical and behavioral research in the United States. During a period of budget balancing in which many federal programs took serious budget hits, the NIH, including NIMH, has received substantial increases.

The Congress has asked, and I think that all of you, as taxpayers also should ask, whether the NIH appropriation has been used wisely. I have talked a bit about how we are trying to identify and support high impact research, in part by dialogues with constituency groups. But I want to give you another perspective on how well we are investing NIMH dollars, and to do so requires a little bit of history.

As some of you recall, NIMH, along with the National Institute on Drug Abuse and the Alcohol Institute, used to be part of a separate agency called ADAMHA, the Alcohol, Drug and Mental Health Administration.

In 1992, a law was passed that reunited NIMH with the rest of NIH; it mainstreamed NIMH with the Institutes focused on cancer, heart disease, arthritis, and so forth. Clearly, in the interest of equity, parity, mainstreaming, lack of discrimination, and other issues important to all of us, the merger with NIH was symbolically important. But many of the scientists that we support were very concerned about being part of the larger NIH pool, because the stigma that accrues to the diseases also accrued in some ways to the scientists who study these diseases. There was a sense that cancer biology is more mature, and there was a reasonable concern about competing with investigators who are essentially working with single cells; that is, single cell types that comprise a given organ. NIMH scientists deal with the brain, the most complex organ in the known universe and its interaction with our mental life, our behavior, our context, our environment, our development. Was our science mature enough to compete? For the first several years after the merger of the former ADAMHA Institutes with NIH, the legislation allowed our Institutes to maintain separate peer review systems. Well, one of the things that I felt strongly about was that we owe you and all of America the very best research and I was confident that the best research would arise in an open competition.

So, I worked with my colleagues in the established NIH research institutes, including the Neurology Institute, Child Health and Human Development, Aging, Heart, and others, in starting with a blank sheet of paper to determine how to update, redesign, and improve neuroscience review across all of NIH – and then have all neuroscience applications compete together; with no more "separate but equal" treatment for research targeted to the understanding and treatment of mental disorders. We completed the reworking of neuroscience review processes and then did the same with behavioral science review. Let me clarify that these areas – neuroscience and behavior – are handled differently than our clinical and mental health services review groups. NIMH has retained the latter, and it is on these that we have public members participating. But the new consolidated review groups in neuroscience and behavioral science mix applications for funding from all the various Institutes that

support research in these areas, so all scientists in these disciplines are competing with one another, regardless of to which illness or problem their studies may have ultimate relevance.

We now have under our belts about two years experience with this new shared review in neuroscience, and I am delighted to report that NIMH-funded investigators are doing extraordinarily well – much better, in fact, than we *should* be doing if one anticipated an even spread of grants across Institutes. At NIH, grant applications are percentiled by quality. In the past several consolidated review cycles that we have analyzed, we see that in the top tenth percentile NIH wide, NIMH has accounted for 12 percent and, in some instances, as high as 15 percent of the successful applications; that is, half again as many as we might be expected to have. This has been true in both neuroscience and in behavioral science.

It appears our investigators' initial concern was unfounded. In head-to-head competition with other areas of science, we are actually doing better than we ought to if everything came out equally for every institute. It makes me very proud. Our performance in these areas ultimately benefits all of our constituencies and it should make all of us proud because it reflects remarkable progress in overcoming the stigma that once accrued to every corner of our endeavor.

It also means that as advocates for research on mental disorders and mental health, you can be reassured that if you were to be full throttle in favor of appropriate funding for our field, you can hold that position in good conscience because the quality of the research that NIMH is funding is something that we can all be very proud of.

This year, of course, we are looking ahead to a change in Administrations, and even before the elections, we can we anticipate changes stemming from the announced retirements of some of the key people we work with in Congress. I know that we will retain trusted champions for mental health research as well as find new supporters and I know our success in this will begin, as always, with the quality of the research, the quality of the data that we can bring to the table. And let me note that while competition is healthy for the quality of all research, we need to acknowledge that, ultimately, research pays off for everyone. As I mentioned earlier, in our advocacy, I never want us to pit disease against disease. Every call for medical research is worthy and every family, actually, has more than one affliction.

Let me stop talking and let's take the next 20 minutes or so to have a back and forth. Obviously, you can comment on or ask about anything, not just the topics that I highlighted, which I intended to use as examples in making larger points.

Discussion

AUDIENCE: [Thank you for] being a leader in advancing research in children. My question is one -- this afternoon, I think, Peter Jensen is going to report on some research that really shows that parents all along, parents of children with needs and parents with children that aren't exhibiting symptoms seem to know what the incidence is, seem to know that mental illnesses are real, seem to know that mental illnesses are treatable. Then going back a couple of months ago, at the National Advisory Council, you had a report on this massive ADHD research that seemed to say that medication works a little bit better if it is enhanced with psychotherapy and, again, ADHD is real. But my question is about compliance. When the parents were given the information in the three different -- I think there were three controls, to me the important question is what did they do as a result? Did the ones that were getting the booster continue? Did the ones that were on medication see the value of it and continue -- because it seems that compliance fades and that people are people and they do through different phases and that is the issue. It is the connect between what works and then actually implementing it.

DR. HYMAN: I think you have asked a very important question and you phrase it in terms of kids, but it is a general, it is a critical question. It breaks into two parts. The first is we recognize there is a gap between what we know and what we do. So, we might have all this data, but often, kids or adults don't end up on the right treatments to begin with. We really have to understand that our illnesses are not like a strep throat. You don't take seven days of penicillin and walk away. These are chronic or recurrent illnesses, many of them with roots early in life and lasting throughout life. Sticking with treatment, and changing treatment as you go through different developmental stages of your life is exhausting and, again, not unique to us.

You know, when kids with juvenile diabetes, that is, Type 1 diabetes, reach adolescence, a lot of them don't want to be sick kids. They don't want to take their insulin and they get into an enormous amount of trouble as they are negotiating those issues.

Research on adherence has been a major goal of mine for NIMH. The trouble is it is really hard to do. You know, the usual way that physicians approach adherence is to say "Take your medicine or something bad is going to happen," and this is not very effective, and clearly not a partnership. But getting really good ideas, the right ideas about how we are going to engage not just a kid or an adult with mental illness, but a family, a peer group, a society, to help with adhering to treatments that may be necessary through a lifetime is extremely difficult. We are dealing with situations where an individual doesn't even want to think about treatment, or is just exhausted by every aspect of an illness; situations in which medication has side effects, or when the psychotherapy is confrontational as it might be, for example, in panic disorder. These are all difficult, even terrifying issues that a person understandably might prefer not to face.

One of our goals is to seduce into this and other mental health areas the very best behavioral scientists in the United States, who are mostly hidden away in departments of arts and sciences, working in areas that have nothing to do with the public health. We need to get these people to help us think about influencing human behavior over time. But there is something else that is very important that I think the families of kids with ADHD face maybe more than anybody else in the last year, given all of the headlines, and that is the information that is out there.

Are parents being supported to do things or are parents being made to feel guilty? Are parents ashamed to admit that they have a kid with depression and having to listen to others' critical or snide comments about the child's being in psychotherapy and/or getting medication? Or, are we supporting parents in their efforts to recognize that giving their child a healthy foundation will allow them to learn in school. This is something we need to do as partners. We need to make sure that the right information is out there.

AUDIENCE: -- …We came here enormously desirous and needful of your information. We are your bridge. We do work with those parents. We work with the policy makers. We work with the providers. And one of our problems is access to your materials. There was a suggestion that we should get a few materials and then reproduce them. That is impossible for most of us with our budgets. We simply can't do it. We need your information. We need it in volume and we need it for free. And it is just enormously important to all of us.

DR. HYMAN: We understand this. You know, we have gone around the country listening to people and one of the things we have heard again and again is that you need the information. Also, people who are *not* here need it. The information needs to be in pediatricians' offices and family doctors' offices. The problem, and here, again, this is something that you can help me with, is that the Congress has been enormously generous with money for research studies, but they see all other aspects of our functioning often as, quote, "big government."

Our communications officers are lumped in, as I am, as part of a larger bureaucracy. And the Government Printing Office is seen as part of this. I think it is really important, at least as one step, when you talk to other policy makers, to stress the importance of our role in communicating information generated through research. In fact, it is a role that was mandated in the original authorizing legislation for NIMH, but if regulations restrict our ability to provide you with the information in forms that you need, we must adhere to those.

We have a great NIMH Web site (www.nimh.nih.gov) but we know that most of the people with whom you are dealing with are not out there visiting the NIMH Web site. Indeed, we need you even more because there is our web site and then there are an equal or greater number of web sites with bad information out there. So, we will try to be as creative as we can within our legal and appropriations constraints, but the public will benefit if you help your legislative contacts understand how your groups will benefit if we have the capacity and authority to communicate better.

AUDIENCE: Good morning. My name is Tom Richardson. I am from Washington State, the home of Microsoft. It strikes me that, in responding to this previous question, that we really ought to be thinking maybe four or five years down the road in terms of how to communicate. I am also something of an environmentalist. I hate seeing us kill any more trees than is necessary, but I think very quickly those people who do need this information, whether it is physicians' offices or waiting rooms will have access to the Web, that all of us that used to just have a telephone and now have all these other gadgets, that will become commonplace, including for families of children with mental illness. I think we ought to be thinking of how to appropriate funding and design a system that works in the digital age, as opposed to having pamphlets produced, that we ought to be focusing in that direction.

DR. HYMAN: I agree with you but I think it is not an either/or because there is still this transitional period. It is very important that you work with us on this, but I also think one of the things I would ask you to think about is something I mentioned in response to the last very good question, which is the fact that while the wonderful thing about the web is the diversity of facts and perspectives it conveys, there is also a lot of incorrect information out there. We don't want to all leave here sort of goose stepping in a single file, but I worry about this and I don't have a good solution. We are not going to agree on every last detail, but I think we can agree on what good information is.

I am not expecting an answer right now but we all need to think about ways of helping consumers as well as policy makers gain good information? Again, there is a very poignant set of examples out there. One is the information now bombarding parents of kids getting psychotropic drugs; many of the headlines have been making families feel awful. Another is the controversial view we see being reported in the press that HIV does not cause AIDS. We recently have seen this view endorsed by the Prime Minister in South Africa, and, as a result, despite the fact that 10 percent of South Africans are infected, last year that country's public health system decided not to give AZT to mothers about to give birth, even though we know that AZT in low dose regimens can block transmission.

So, this issue in this information age, how we get above the clutter and get good information that we can agree on out there—it is a very important problem to me.

AUDIENCE: -- having the data, but people don't always apply it or use it well. You have talked a little about being hamstrung in terms of some of your communications opportunities and maybe not having the budget. My question really is one about training and the need, whether it is physicians, social workers, psychiatrists, psychologists, others, to really have the information in terms of what kinds of strategies is NIMH thinking about in terms of doing more so that the data is out there to the providers.

One other question, which really has to do with research strategies. You talked about wanting to move away from the research one, kind of academic health center institutions and thinking about what ways some of the people here around the table can really work with NIMH to get people who do not necessarily think of themselves as researchers, but have access to that greater diversity of patients to be able to actually do that kind of research.

DR. HYMAN: Okay. Let me just partially answer the first question, which is about education.

I think one of the things that we have learned, perhaps not surprisingly, but disappointingly over the last five or six years, was that guidelines and continuing medical education or continuing nursing education or whatever in service, really has much less of an impact on provider behavior across disciplines than one would want.

The one benefit that everyone agreed managed care could have was its potential to encourage shared high standards for practice, so-called evidence-based practice. I will not comment on the downside, which involves a focus on managed *cost* rather than managed *care*.

But what we found is that with all of the tools at the disposal of managed care, HMOs and so forth, evidence-based practice hasn't happened. Of course, we are going to continue to provide information that professional societies can use to make guidelines and curricula. But, again, you know, I think this is a research issue. Understanding how we change provider behavior is an issue for behavioral science and if we don't face up to it, we are going to fail in all of medicine. The example about treating peptic ulcers is one I love because it is clear -- if you treat an ulcer with triple antibiotics, it doesn't come back. If you treat it with Tagamet alone, you feel better for a few weeks and then it comes back. Yet, you know, it has taken a decade to get most providers to change their behavior and some still have not. People often say physicians are conservative. But people are very busy and we need to understand how to get them to stop and learn.

Now, a second partial answer to this very thoughtful comment is that the informed consumer helps people to learn. A lot of docs are very uncomfortable when somebody shows up in the office and they have read off the Web or the Tuesday Science Times about a new treatment or about a new study comparing treatments and they haven't read it. This gets back to your issue about information. We need well-informed consumers because that creates a pressure. In terms of getting sites involved in research, this is a difficult problem because we clearly need to do research in sites outside of academic health centers because that is where most people get their care, but a lot of people are not research trained, research savvy, and you don't want to do research that doesn't give you good answers.

It is going to be a long process that I think is going to require partnerships between our usual research constituencies and people in other settings. We have begun to set some of those up. I think our new clinical trials program is a good stalking horse for some of these issues.

AUDIENCE: Good morning. Greetings from Arizona, Dr. Hyman. Cheryl Becker from the Mental Health Association of Arizona. For 20 years we have been cautioned, I think, cautioned not to say that mental illness is curable but today with all the wonderful advances that have been made, I am wondering what your recommendations are in terms of [talking about] cure?

DR. HYMAN: Okay. Well, we are not yet in a position to cure mental illnesses. Our treatments are good but we are not in a position to cure. Indeed, if anything in our current clinical research pipeline worked out beyond our wildest dreams, we still wouldn't be curing people. That is why we do have a portfolio, some short term investments and some long term investments. That is why we are so invested in genetics, in basic neuroscience, and basic behavioral science.

My feeling is that – and I don't want to over-promise – but that over the next decade, we will begin to see our way toward cures and we can have no other goal but cures and prevention. Now, lest this be empty rhetoric, I am going to tell you something.

Alzheimer's disease, which 10 years ago was considered absolutely a hopeless result of aging, today, as a result of wonderful findings through genetics and molecular neurobiology, has a pathogenesis which is being uncovered, and we now believe we at least understand the culprit in killing nerve cells in the brain, something called the A-beta peptide of beta amyloid. We know that because by working with families who had early onset genetic Alzheimer's disease, investigators found that defects in the processing of this little protein fragment can cause Alzheimer's disease. As a result, every substantial drug company in the United States is now working on inhibitors of these processing enzymes, the so-called beta and gamma secretases.

It is possible, although not certain, that five years from now we will have in clinical trials, drugs that can stop in its tracks the progression of Alzheimer's disease. We should have no less a set of goals for schizophrenia, manic depressive illness, autism, depression and the anxiety disorders. We don't know where it is going to come from, but we cannot rest until we have exhausted every possibility looking for a cure.

In essence, you know, I have had this well-publicized disagreement with one notable research advocate, who doesn't think we should be doing basic research or basic neuroscience. I think that would be selling everyone short. While we continue to do our current clinical research in a way that is responsive and appropriate, we also need to be making these longer term investments.

AUDIENCE: Dr. Hyman, Mary Rappaport from NAMI. Going back to the issue of kids and all the sensationalism that has occurred, especially over the last year, and your comment about shifting the nexus to where the real issue is in terms of who is treating them and how are they treating and are they trained, which I agree with, however, there is a divide between those two things. And those have to do with the questions that come up in terms of safety, long term -- the implications of long term use, the side effects, the vehement opponents toward medicating kids, who claim, you know, it results in violence and suicide. What we need as an organization, and I would guess most of us around here do, are science-based messages to at least respond, if not refute some of this.

DR. HYMAN: I agree and in many cases the data is in. In the case of very long term studies, of course, we really want to know what the impact of an SSRI or of Ritalin is over ten years. Of course, in pursuing those answers, we also meet ethical problems, right? How do you have a kid in an experiment, as opposed to just a naturalistic follow-up for so long? You know, inevitably you have to weigh the rights and the needs of an individual child versus the public health issues coming from experiments. So, the fact is we don't have this very, very long term data.

I think framing messages is also very important. Despite the shorter term, you know, 14 month data, showing incredible safety and efficacy for Ritalin in the treatment of ADHD, for example, people will argue that there are unknown dangers of long term use. We have to remind them of the very known dangers of having an untreated mental disorder. If we are worried, as we should be -- you know, I don't want to make light of it, about the impact of medications on brain development -- we should be equally worried about the impact on brain development of having depression and not being able to learn in school.

Even though there is a theoretical possibility that a psychotropic drug might lead to suicide, although there is no data at all for that, we should look at the fact that suicide today caused by depression and other conditions today is the second or third leading cause of death of children. So, we

need to frame messages that exploit the data that we do have, that I think would be very, very powerful. I think that is one of the very reasons why we are all here together.

Thank you.

END.